



SECRETARÍA DE
AGRICULTURA, GANADERÍA,
DESARROLLO RURAL, PESCA Y ALIMENTACIÓN

SAGARPA

Consejería Agroalimentaria para EUA

Washington, D.C. August 29, 2002

- Docket No. 02N-0276

Joseph Levitt
Director, Center For Food Safety and Applied Nutrition
Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion
On the Promulgation of Regulations to Implement Provisions of the Bioterrorism Act of 2002 - -
Registration of Food Facilities (Section 305) - - Docket No. 02N-0276

Dear Mr. Levitt:

On behalf of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion ("SAGARPA") of the Government of Mexico, we would like to submit comments identifying the principal concerns of SAGARPA over the implementation of the Registration of Food Facilities provision (Section 305) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act of 2002").

Section 305 would amend the Food, Drug and Cosmetics Act ("FDCA") by adding a new Section 415, requiring both U.S. and foreign facilities involved in the manufacturing, processing, packing or holding of food for consumption in the U.S. to register with the FDA. The registration is to contain the names and addresses of each facility in which the registrant operates, and all trade names used by the registrant. Imported food found to be from a facility which has not registered under this provision will be denied entry into the United States until that foreign facility has registered under this Section.

SAGARPA's primary concern with respect to this provision is that it not be overly burdensome for foreign facilities, and that it not be used as an impediment to the importation of food products into the United States.

To minimize the burden on foreign facilities that are required to register under this provision, SAGARPA would make the following suggestions:

1. To the extent that foreign facilities can show that they have already registered with other U.S. government agencies (for instance, numerous foreign agricultural concerns has registered with the U.S. Department of Agriculture for quality or quarantine purposes, or under various APHIS/USDA programs), and that they have already provided the same information in these prior registrations being requested by Section 305, they should not have to re-register with the FDA. These existing registration should be incorporated into the list of registered facilities Congress has instructed the FDA to create and maintain under the Bioterrorism Act, and no prior regulations should be deemed sufficient to comply with the provisions of new Section 415.

02N-0277

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2. The regulations promulgated by the FDA should provide that foreign facilities can register with the FDA through their governments, and should contain procedures which would permit foreign governments to register covered facilities within their jurisdiction with the FDA. Small and even medium companies simply may not have the resources or expertise to deal directly with a U.S. government agency, and may find it much less burdensome (often much less overwhelming) to deal with their own government rather than the U.S. government.

3. The regulations should also contain procedures that would permit foreign facilities to register with the FDA through U.S. Consulates or the U.S. Embassy located in the country. This again will make it much easier for smaller and less sophisticated foreign facilities to comply with this requirement. SAGARPA notes that new Section 415 provides that a registrant is to notify the FDA in a "timely manner" of any changes to its registration. SAGARPA would strongly urge that the regulations provide a specific period of time in which such changes must be reported to the FDA, and would further suggest that such period be no less than 30 days.

Further, SAGARPA suggests that it would be useful if the regulations could address and clarify the following issues:

1. If an entity owns or operates numerous facilities or companies engaged in covered activities, can it simply file one registration with the FDA listing all covered facilities/operations (even if separately incorporated and/or operated), and if so, would that registration or registration number be sufficient to cover all covered facilities/operations?

2. When facilities are be leased to an exporter or shipper, should the registrant be the owner of the facility, or the lessee who is actually exporter or shipper of the product?

3. What is an exporter or shipper to do with the registration once it has been received from the FDA? Must the registration document (or a copy thereof) accompany each shipment to the United States, or is the registration number sufficient? In the latter case, is the registration number to be placed on a specific import document? If so, where? Is it to be placed on the product itself or its outermost packaging. Again, if so, where?

SAGARPA appreciates the opportunity to express its concerns and views at this early stage of the rule-making process. SAGARPA would welcome the opportunity to meet with the appropriate FDA officials to further discuss its views and concerns.

Sincerely,

Enrique Lobo
Minister
Agricultural Office